MIRIAD: **M**other **I**nfant **R**apid **I**ntervention **A**t **D**elivery

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Perinatal Grantees Meeting

Round Table Discussion

BACKGROUND:
Voluntary Intrapartum Rapid HIV Testing for Women with Inadequate Prenatal Care

- Most HIV-positive women in the U.S. deliver in a hospital
- In the absence of adequate prenatal care, rapid testing for HIV during the peripartum period offers a crucial opportunity for health care intervention for both mother and infant
- Such policy appears cost-effective, especially in hospitals with maternal HIV seroprevalence above 0.7% (Am J Ob Gyn 1999;181:1062)
- How best to provide rapid HIV testing and treatment options needs systematic research
- Lessons learned in MIRIAD will assist in formulating best-practice recommendations in the U.S. for women presenting late in pregnancy
- Rapid HIV testing and start of ART prophylaxis during labor may be an important HIV prevention strategy for high-risk perinatal populations elsewhere in the world.

CDC MIRIAD Project Description

- Limited to institutions with relatively high HIV prevalence (0.8% - 4%) among child bearing women
- Five primary sites: Atlanta, Chicago, Miami, Louisiana, and New York City
- Funded in October 1999 with pilot phase in Spring 2001. Enrollment to begin in late Summer/Fall of 2001.
- Plans to screen 6,000-8,000 women for HIV late in pregnancy and identify and offer ART to 100-140 HIV-infected women per year.
- The collaboration with PACTG 1031 sites has the potential to screen an additional 5,000-10,000 high-risk women and identify 50-100 HIV-infected women a year at US sites. The international PACTG sites could increase these numbers substantially.

MIRIAD CDC Sites and Hospitals

New York
Bronx-Lebanon
Harlem
Jacobi
N. Central Bronx

Chicago
Cook County
Bethany
St. Bernard
Provident

Atlanta
Grady

Louisiana
Charity (New Orleans)
Earl K. Long (Baton Rouge)

Miami
Jackson Memorial
Homestead*
Deering*
Parkway Regional*

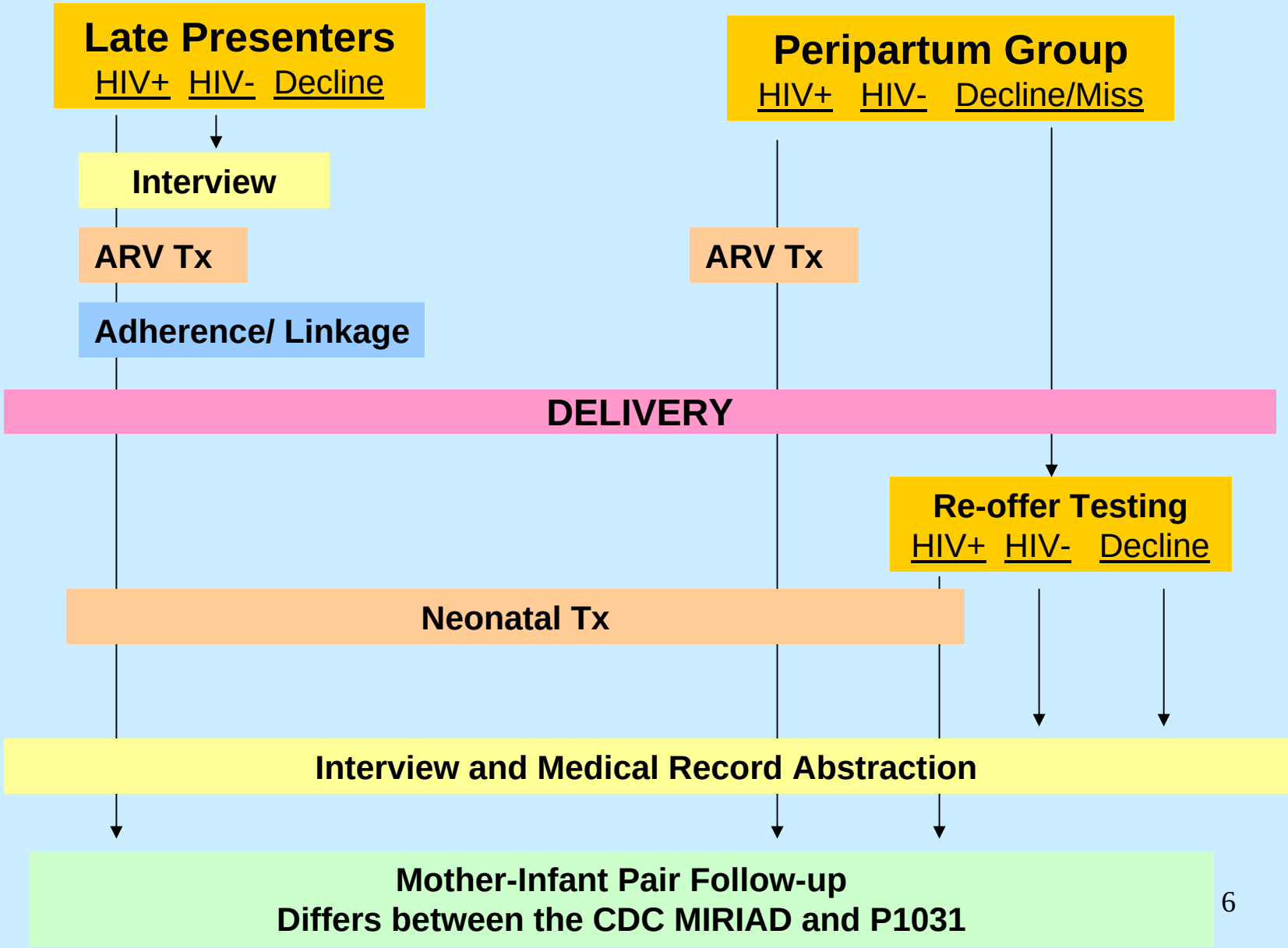
* Tentative participation in 2002

Objectives of the core CDC MIRIAD protocol to be done in collaboration with PACTG (P1031)

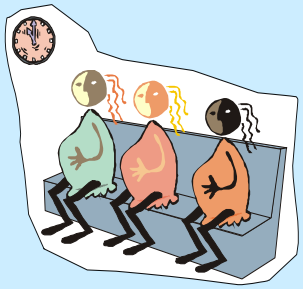
This protocol will assess:

1. **The feasibility and acceptance of voluntary rapid HIV testing among pregnant women with unknown HIV serostatus who present in labor or late to care (≥ 34 weeks gestation)**
2. **Rapid ART given in labor and delivery or to the neonate**
3. **The performance of rapid HIV tests in the perinatal setting**
4. **Barriers to prenatal care and HIV testing**
5. **The rate of HIV transmission and the risk relative to the timing of initiation of ART**
6. **Trends in maternal virologic response and the development of viral resistance after initiation of short-course ART**
7. **Adherence to post-partum medical care of mother and infant for 6 months.**

The MIRIAD Core Rapid Testing and Treatment Protocol



MIRIAD Peripartum Group: Events Leading to Prevention Success



Present to L&D with unknown HIV status

Informed consent using flip charts for comprehension

Rapid testing performed. Results in ~20-40 minutes.

Provide results and post-test counseling before or after delivery (per patient preference)

If HIV +, ARV treatment ASAP

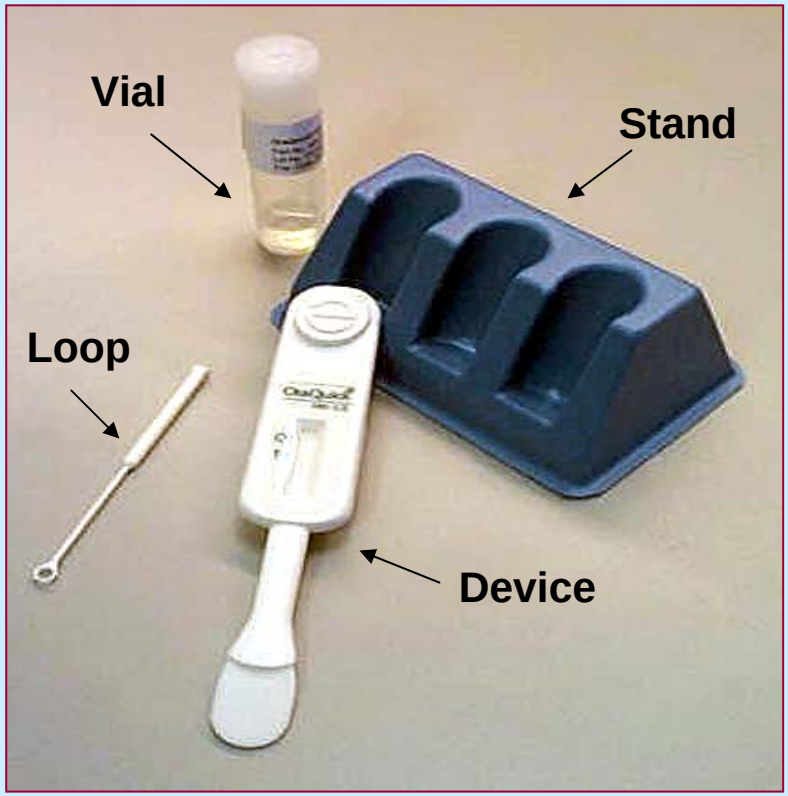
Follow-up care for both woman and infant

Proposed MIRIAD Tests Based on Current Availability

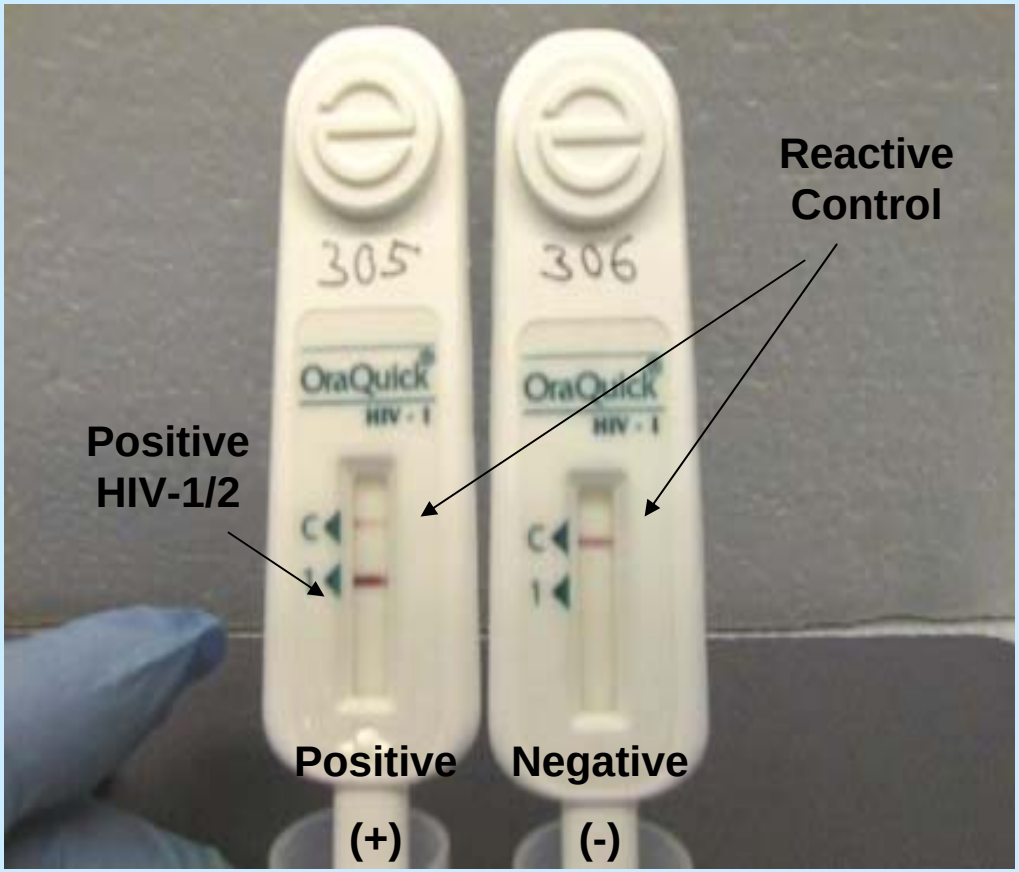
Initiation of therapy will be based on results of the OraQuick assay performed on whole blood.

A treatment Investigational Device Exemption (IDE) for OraQuick is currently pending approval by FDA.

Different rapid testing algorithms may be evaluated as other rapid tests become available (either under Treatment IDE or with FDA approval).



OraQuick



Read results in 20 Minutes

OraQuick has been shown to perform better than both SUDS and EIA.

Test results, specimens collected from 340 known HIV+ and 467 HIV- persons

Test	Ref Positive	RT Positive	False Negative	Ref Negative	RT Negative	False Positive	Sensitivity	Specificity
OraQuick1	340	340	0	464	463	1	1.000	0.998
OraQuick RR	340	340	0	464	463	1	1.000	0.998
SUDS1	340	337	3	467	462	5	0.991	0.989
SUDS RR	337	334	3	467	465	2	0.991	0.996
EIA 1	340	340	0	467	442	25	1.000	0.947
EIA RR	340	340	0	467	463	4	1.000	0.991

*Ref = Reference; RT = Rapid test; OraQuick1 = Result of 1st OraQuick test; SUDS1 = results of 1st SUDS test; EIA1 = results of 1st EIA; RR = Repeatedly reactive

Branson, et al. Unpublished data.

The Influence of Seroprevalence on Positive Predictive Value (PPV)

Test Specificity 99.8%

HIV Prevalence	Positive Predictive Value
10%	98%
5%	96%
2%	91%
1%	83%
0.5%	71%
0.3%	60%
0.1%	33%

Opportunities of a CDC-PACTG Collaboration in MIRIAD

- Explore the feasibility of obtaining informed consent during labor and the impact of interventions to reduce perinatal HIV transmission.
- P1031 sites in the U.S. can gain access to rapid HIV diagnostic tests that are otherwise unavailable for clinical use.
- The speed with which core MIRIAD objectives are met may greatly increase.
- The P1031 team plans specific sub-studies, e.g., prevention of postpartum NVP resistance using maternal HAART